



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Secretary's Advisory Committee on  
Human Research Protections  
Washington, DC 20201

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DEC 04 2013

The Honorable Kathleen Sebelius  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Ms. Sebelius:

On behalf of the Secretary's Advisory Committee on Human Research Protections (SACHRP), I respectfully submit for your consideration comments relevant to the Department of Health and Human Services (HHS) human subjects protection regulations at 45 CFR part 46. These comments, originating in the Subcommittee for Harmonization, were passed by SACHRP at their July 2013 meeting.

**Recommendations from the Subcommittee on Harmonization**

On October 28, 2009, SACHRP approved a recommendation establishing a Subcommittee on Harmonization (SOH). SACHRP's charge to this subcommittee was to identify and prioritize areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. The Subcommittee will develop recommendations for consideration and possible adoption by SACHRP, to harmonize and simplify these guidelines and regulations. The goal of this subcommittee effort is to reduce unnecessary burdens on research efforts, thus resulting in better allocation of research resources and promoting the safety and welfare of human subjects.

On July 11 SACHRP passed the attached comment regarding the June 4, 2013 FDA Request for Comment relating to the availability of masked and de-identified non-summary safety and efficacy data.

On behalf of SACHRP, I would like to thank you for your consideration of this report. The committee, the Subpart A Subcommittee and the Subcommittee on Harmonization have been actively working in pursuit of their charges, and we look forward to continuing this work to enhance human subjects protections for the benefit of all Americans.

Sincerely,

/signed/

Jeffry R. Botkin, M.D.  
Chair, Secretary's Advisory Committee  
on Human Research Protections  
(SACHRP)

cc: Jerry Menikoff, M.D., J.D., Executive Secretary, SACHRP  
Julia Gorey, J.D., Executive Director, SACHRP